Complete Summary

GUIDELINE TITLE

Cardiovascular disease. In: Menopause and osteoporosis update 2009.

BIBLIOGRAPHIC SOURCE(S)

Cardiovascular disease. In: Menopause and osteoporosis update 2009. J Obstet Gynaecol Can 2009 Jan;31(1 Suppl 1):S11-8. [71 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Turek M, Blake J. Cardiovascular disease. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S81-5. [54 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Menopause
- Cardiovascular disease

GUIDELINE CATEGORY

Management Prevention Risk Assessment

CLINICAL SPECIALTY

Cardiology Endocrinology Family Practice Internal Medicine Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Health Care Providers
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

To provide updated guidelines for health care providers on the management of menopause in asymptomatic healthy women as well as in women presenting with vasomotor symptoms or with urogenital, mood, or memory concerns, and on considerations related to cardiovascular disease, breast cancer, and bone health, including the diagnosis and clinical management of postmenopausal osteoporosis

TARGET POPULATION

- Menopause in asymptomatic healthy women
- Menopause in women presenting with vasomotor symptoms, urogenital, sexual, and mood and memory concerns and specific medical considerations, and cardiovascular and cancer issues

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Address risk factors for stroke in all postmenopausal women:
 - Diabetes mellitus
 - Hypertension
 - Abdominal obesity
 - Current cigarette smoking
 - Psychosocial stress
- 2. Hormone therapy (HT)
 - Low dose estrogen
 - Ultra-low dose estrogen

MAJOR OUTCOMES CONSIDERED

- Cardiac events
- Premature loss of ovarian function
- Coronary artery disease (CAD)
- Diabetes and metabolic syndrome
- Stroke

Venous thromboembolism (VTE)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE was searched up to October 1, 2008, and the Cochrane databases up to issue 1 of 2008 with the use of a controlled vocabulary and appropriate key words. Research-design filters for systematic reviews, randomized and controlled clinical trials, and observational studies were applied to all PubMed searches. Results were limited to publication years 2002 to 2008; there were no language restrictions. Additional information was sought in BMJ Clinical Evidence, in guidelines collections, and from the Web sites of major obstetric and gynaecologic associations worldwide.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Quality of Evidence Assessment*

- I: Evidence obtained from at least one properly randomized controlled trial.
- **II-1**: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.
- **II-3**: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

^{*} Adapted from the Evaluation of Evidence criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The authors critically reviewed the evidence and developed the recommendations according to the methodology and consensus development process of the Journal of Obstetrics and Gynaecology Canada.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations*

- **A.** There is good evidence to recommend the clinical preventive action
- **B.** There is fair evidence to recommend the clinical preventive action
- **C.** The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- **D.** There is fair evidence to recommend against the clinical preventive action
- E. There is good evidence to recommend against the clinical preventive action
- **L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

^{*}Adapted from the Classification of Recommendations criteria described in: Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The rating scheme is defined at the end of the "Major Recommendations" field.

- 1. Health care providers should not initiate or continue hormone therapy (HT) for the sole purpose of preventing cardiovascular disease (CVD) (coronary artery disease [CAD] and stroke). (IA)
- 2. Health care providers should abstain from prescribing HT in women at high risk for venous thromboembolic disease (IA)
- 3. Health care providers should initiate other evidence-based therapies and interventions to effectively reduce the risk of CVD events in women with or without vascular disease. (IA)
- 4. Risk factors for stroke (obesity, hypertension, and cigarette smoking) should be addressed in all postmenopausal women. (IA)
- 5. If prescribing HT to older postmenopausal women, health care providers should address cardiovascular risk factors; low- or ultralow-dose estrogen therapy is preferred. (**IB**)
- 6. Health care providers may prescribe HT to diabetic women for the relief of menopausal symptoms. **(IA)**

Definitions:

Quality of Evidence Assessment*

- **I**: Evidence obtained from at least one properly randomized controlled trial.
- II-1: Evidence from well-designed controlled trials without randomization.
- **II-2**: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.
- **II-3**: Evidence from comparisons between times or places with or without the intervention. Dramatic results from uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Classification of Recommendations**

- **A.** There is good evidence to recommend the clinical preventive action
- **B.** There is fair evidence to recommend the clinical preventive action

- **C.** The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
- **D.** There is fair evidence to recommend against the clinical preventive action
- **E.** There is good evidence to recommend against the clinical preventive action
- **L.** There is insufficient evidence (in quantity or quality) to make a recommendation; however, other factors may influence decision-making
- *The quality of evidence reported in these guidelines has been adapted from the Evaluation of Evidence criteria described in the Canadian Task Force on Preventive Health Care.***
- **Recommendations included in these guidelines have been adapted from the Classification of Recommendations criteria described in the Canadian Task Force on Preventive Health Care.***
- ***Woolf SH, Battista RN, Angerson GM, Logan AG, Eel W. Canadian Task Force on Preventive Health Care. New grades for recommendations from the Canadian Task Force on Preventive Health Care. Can Med Assoc J 2003;169(3):207-8.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate management of cardiovascular disease risks during menopause

POTENTIAL HARMS

- Oral hormone therapy (HT) results in an increased risk of venous thromboembolism that is greatest in the first few years after the start of therapy
- Available evidence demonstrates that initiation of HT should be done with caution in women with distressing vasomotor symptoms who are more than a decade after menopause because it may be associated with an increased risk of adverse cardiac events. Attention to correction of underlying cardiovascular risk factors before initiation of HT would be important in these isolated cases.
- Hypertension and other risk factors for stroke are common in postmenopausal women. HT appears to slightly increase the risk of ischemic stroke, and

- caution should be taken to manage hypertension and other risk factors in women seeking treatment for distressing vasomotor symptoms
- There was a significant elevation in the incidence of cardiovascular events in combined estrogen and progestogen therapy (EPT) users compared with women receiving a placebo in the first year of therapy.

CONTRAINDICATIONS

CONTRAINDICATIONS

Hormone therapy (HT) should not be used for primary or secondary cardioprotection

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed. Local institutions can dictate amendments to these opinions. They should be well documented if modified at the local level. None of these contents may be reproduced in any form without prior written permission of the Society of Obstetricians and Gynaecologists of Canada (SOGC).

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Cardiovascular disease. In: Menopause and osteoporosis update 2009. J Obstet Gynaecol Can 2009 Jan;31(1 Suppl 1):S11-8. [71 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Feb (revised 2009 Jan)

GUIDELINE DEVELOPER(S)

Society of Obstetricians and Gynaecologists of Canada - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Obstetricians and Gynaecologists of Canada

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Principal Authors: Robert L. Reid, MD, FRCSC, Kingston ON; Jennifer Blake, MD, FRCSC, Toronto ON; Beth Abramson, MD, FRCPC, Toronto ON; Aliya Khan, MD, FRCPC, Hamilton ON; Vyta Senikas, MD, FRCSC, Ottawa ON; Michel Fortier, MD, FRCSC, Quebec QC

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following conflicts of interest have been disclosed by the authors.

Dr Reid: Speaker or consultant to Wyeth, Bayer, Organon, Proctor and Gamble, Novo Nordisk; advisory boards: Paladin, Wyeth; research support: Organon, Bayer.

Dr Blake: Speaker or consultant to Wyeth, Merck, Glaxo Smith Kline, Bayer; advisory boards: Bayer, Wyeth and Lilly, Novo Nordisk.

Dr Abramson: Speaker or consultant to Abbott, Astra Zeneca, Boehringer Ingelheim, Bristol Myer Squibb, Dupont, Eli Lilly, Lifespeak, Norvartis, Fournier, Merck Frosst, Pfizer, Servier, Schering, Sanofi-Aventis; advisory boards: Astra Zeneca, Boehringer-Ingelheim, Novartis, Pfizer, Sanofi-Aventis; research support: Astra Zeneca, Boehringer Ingelheim, Merck.

Dr Khan: Speaker or consultant to Amgen, Merck, Lilly, Novartis, Servier, Proctor and Gamble; research support: Merck, Lilly, Novartis, Alliance for Better Bone Health.

Dr Senikas: None declared.

Dr Fortier: Speaker or consultant to Proctor and Gamble, Merck; advisory boards: Amgen, Bayer, Novo Nordisk, Novartis, GlaxoSmith Kline, Lilly, Paladin; research

support: Wyeth, Sanofi.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Turek M, Blake J. Cardiovascular disease. In: Canadian consensus conference on menopause, 2006 update. J Obstet Gynaecol Can 2006 Feb;28(2 Suppl 1):S81-5. [54 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Society</u> of Obstetricians and Gynaecologists of Canada Web site.

Print copies: Available from the Society of Obstetricians and Gynaecologists of Canada, La société des obstétriciens et gynécologues du Canada (SOGC) 780 promenade Echo Drive Ottawa, ON K1S 5R7 (Canada); Phone: 1-800-561-2416

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on April 30, 2009. The information was verified by the guideline developer on May 21, 2009.

COPYRIGHT STATEMENT

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.quideline.gov/about/inclusion.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

Copyright/Permission Requests

Date Modified: 6/15/2009

